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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,653	08/03/2001	Masaharu Noda	31671-173164	6043

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EXAMINER
TON, THAIAN N

ART UNIT	PAPER NUMBER
1632	13

DATE MAILED: 04/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,653	NODA ET AL.	
	Examiner	Art Unit	
	Thai-An N. Ton	1632	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 24, drawn to null mutant non-human animals wherein the function of the Na_v2 gene is deficient, and a method of using the non-human animal in screening, classified in class 800, subclass 3, 13.

II. Claims 5-8, 17, 18 and 30 drawn to a gene that codes for a protein acting as a sensor of extracellular sodium ion level and host cells, classified in class 536, subclass 23.1.

III. Claims 9-13, and 26-28, drawn to a protein that acts as a sensor of extracellular sodium ion level, a fusion protein created by combining the protein with a marker protein and/or peptide tag, and medical compound containing the protein, classified in class 530, subclass 350+, for example.

IV. Claims 14-16 and 29 drawn to an antibody which specifically combines with a protein acting as a sensor of extraceullar sodium level, classified in class 530, subclass 387.1+.

V. Claims 19-21, 31 and 32, drawn to a transgenic non-human animal with excessively expresses a protein acting as a sensor of extracellular sodium ion level, and methods of screening using the non-human animal, classified in class 800, subclass 13.

VI. Claims 22-23, drawn to methods of screening a material that promotes or suppresses the function or the expression of a protein acting as a sensor of extracellular sodium ion level, classified in class 435, subclass 4.

VII. Claim 25, 33 and 34, drawn to a material that promotes or suppresses the function of a protein acting as a sensor of extracellular sodium ion level, and a medical compound comprising the material, unclassifiable.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are to distinct products. The null mutant non-human animal of Invention I can be used to observe gene function, or as a model for disease or condition. The DNA of Invention II can be used to produce protein *in vitro*.

Invention I and any of Inventions II-VII are mutually exclusive and independent. The null mutant non-human animal of Invention I is not required for the protein of Invention III, the antibody of Invention IV, the transgenic non-human animal of Invention V, the methods of screening of Invention VI, and the material of Invention VII, and vice versa.

Invention II and either of Inventions III of Invention IV are distinct products. The gene of Invention II is distinct in chemical structure and function from the protein of Invention III and the antibody of Invention IV. The nucleic acid of Invention II can be used as detection probes, the protein of Invention III can be used for antigen presenting cell priming and the antibody of Invention IV can be used in immunological assays.

Invention II and Invention V are to distinct products. The nucleic acid of Invention II can be used to produce protein in vitro; the transgenic animal of Invention V can be used to observe gene function, or as a model for disease or condition.

Inventions II and VI are mutually exclusive and independent. The gene that codes for a protein acting as a sensor of extracellular sodium ion level and host cells are not required for the methods of screening of Invention VI, and vice versa. In

particular, Invention VI does not require that the cell used in the screening method be transfected with the gene of Invention II, and thus, could be a wild-type cell.

Invention II and VII are mutually exclusive and independent. The gene of Invention II is not required for the material of Invention VII, and vice versa.

Inventions III and IV are distinct because they are of separate uses. The protein of Invention III can be used in a protocol to produce hybridomas, and the antibody of Invention IV can be used in immunological assays.

Invention III and any of Inventions V-VII are mutually exclusive and independent inventions. The protein of Invention III is not required for the transgenic non-human animal of Invention V, the methods of screening of Invention VI, and the material of Invention VI, and vice versa.

Invention IV and any of Inventions V-VII are mutually exclusive and independent inventions. The antibody of Invention IV is not required for the implementation of the transgenic non-human animal of Invention V, the methods of screening of Invention VI, and the material of Invention VI, and vice versa.

Invention V and either of Inventions VI or VII are mutually exclusive and independent. The transgenic non-human animal of Invention V is not required for the implementation of the methods of Invention VI and the material of Invention VII, and vice versa.

Inventions VI and VII are independent because they have separate uses. The methods of screening can identify an array of materials and the material can be used in different methods, such as therapy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT
Thái-An N. Ton
Patent Examiner
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